Number/Name:	P-18-0078 /	

Updated 8/22/2018 with POD for Land (LOAEL of 100 mg/kg-day) and MOE calculations. See calculations below and updated conclusions in red. See Post-Focus memo for rationale of POD selection.

### SUMMARY INFORMATION

EPA estimated the human health hazard of this chemical substance based on its estimated physical/chemical properties and other structural information. EPA concludes there is low-to-moderate concern for human health hazard for the chemical substance.

Based on the hazard determination and available qualitative risk information, EPA concludes that there is risk for the PMN substance. The risk estimates for this PMN are for the intended conditions of use. Other conditions of use and their risks were not evaluated.

### Human Health Hazard:

- Absorption of the low MW fraction
- Concern for developmental toxicity, based on the presence of the PMN based on the average MW) in the chemical structure.
- Potential epoxide concerns are low, as polymer; however, if made differently, there may be a higher percentage of epoxides that could change the hazard call.

## **Human Health Risk:**

- Risks were not identified for workers for developmental toxicity via dermal contact based on analogue data (MOE=1481, Benchmark MOE=1000)
- Risks were not identified for workers for developmental toxicity via inhalation based on analogue data (MOE=2128, Benchmark MOE=1000).
- Risks were not identified for general population for developmental toxicity based on analogue data (All MOEs>10,000, Benchmark MOE=1000).

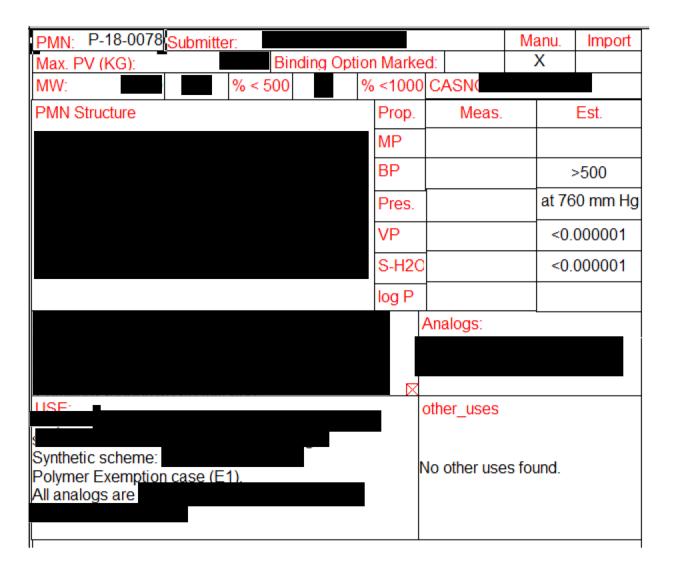
### **Testing Recommendations:**

 OECD Testing Guideline 422, Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test, to clarify the concern for developmental toxicity to workers via inhalation and dermal exposure, and to the general population via drinking water ingestion and fugitive air inhalation.

# PART A

SAT Date: 05 January 2018
SAT Chair: Tracy Behrsing
Health Assessor: Amy Babcock
QC Reviewer: Susan Laessig, 1/10/18

#### Structure:

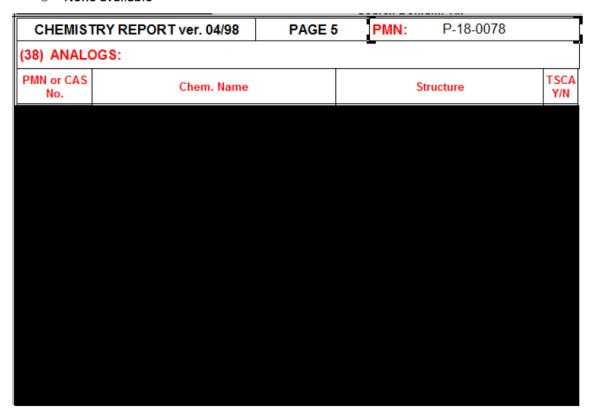


- CASRN:
- Chemical Category:
  - Epoxides
- Chemical Category Health Concerns:
  - Cancer and reproductive effects based on data for several analogous chemicals. There is greater concern for primary epoxides, than for epoxides with substitutions on both of the epoxy carbons.

- Category Testing Strategy:
  - o Lifetime cancer bioassay by the expected route of exposure.
  - o 90-day subchronic with attention to pathology of the reproductive organs.
- PMN Health Rating:
  - o **1-2**
  - o P3 B1 T2
- SAT Key Words:
  - UNCERT DEVEL
- Absorption:
  - Absorption of the low molecular weight fraction
     based on physical/chemical properties.
- SAT Health Summary:

Based the presence of	acids on the po	lymer there is an uncertain po	tential for
developmental concerns	. For the	, this a	acid group would
make up of the PMN	based on the average M	1W. Based on the	and
average PMN moleular v	veight of,	epoxide is expected to be	present on each
polymer and thus poten	tial epoxide concerns are	e low. If made differently. the	re may be a higher
percentage of	acids or epoxides that c	ould change the hazard call.	

- PMN Data: (study summary, POD)
  - None submitted
- Analog Data: (analog, structure, study summary, POD)
  - None available



- Other Information: (structural alert or component of interest, basis, etc.)
  - o SDS
    - Not submitted
- Point of Departure Selected and Basis:
  - o No POD available.

# **Exposure Routes of Interest:**

- \_X\_\_Inhalation
- \_X\_\_Dermal
- \_X\_\_Ingestion

# **PART B**

Focus Date: 22 January 2018 Focus Assessor: Amy Babcock QC: Sailesh Surapureddi

# **USES and EXPOSURES:**

•	Uses:	
	. Synthetic scheme:	

# • Worker Exposure:

o **Inhalation:** mg/d (non-volatile)

o Dermal: mg/d

# • General Population Exposure:

o **Drinking Water:** mg/kg/d

o **Fish:** Below modeling thresholds

o **Air/Inhalation**: mg/kg/d = ug/m3 (fugitive air)

Exposure Scenario <sup>1</sup>			W	'ater		Landfill	Stac	Fugitive Air			
	Drinkin	g Water	Fish Ing	gestion	7Q10 <sup>4</sup>	PDM Days	LADD	ADR	LADD	ADR	LADD
Release activity(ies) <sup>2</sup> ; exposure calculation(s) <sup>3</sup>	ADR	LADD	ADR	DR LADD CC = N/A		Exceeded	LADD	(24-hr conc.)	(Annual conc.)	(24-hr conc.)	(Annual conc.)
	mg/kg/day mg/kg/day mg/kg/day mg/kg/day		mg/kg/day	μg/l	# Days	mg/kg/day	mg/kg/day (μg/m³)	mg/kg/day (μg/m³)	mg/kg/day (μg/m³)	mg/kg/day (μg/m³)	
MFG: Max ADR	1.41E-02		-								
MFG: Max LADD		4.17E-06									

• Consumer Exposure: No identified consumer exposures

## **RISK CALCULATIONS:**

## **Worker Calculations:**

• Risks were not identified for workers for developmental toxicity via dermal contact based on analogue data (MOE=1481, Benchmark MOE=1000)

 Risks were not identified for workers for developmental toxicity via inhalation based on analogue data (MOE=2128, Benchmark MOE=1000).

Focus Worker Calculations MOE = (POD x Abs Rate) / ((PDR x Abs Rate) / BW) Acceptable MOE ≥1000																
Exposure Scenario s and Values <sup>1</sup>	POD= N/LOAEL (mg/kg/ day)	1 1	POD Route Absorp . Adj <sup>2</sup>		Potential Dose Rate (mg/day)		Exposure Route Absorp Adj <sup>2</sup>		Structural Alert/ Component as % of PMN		Avg BW <sup>3</sup> All Adults, 80 (kg)			Margin of Exposure <sup>4</sup> (POD/PMN Dose)	Inhalation Fold" Factor <sup>5</sup> (Benchmark/ MOE)	
WORKER F	RISK		·					_				_				
Highest/Worst Case Doses from Engineering Report													(LOAEL=1000)			
Inhalation	( 100	x	100%	) ÷ (		x	100%	X		÷	80	)	=	2128	N/A	
Dermal	( 100	x	100%	) ÷ (		х	15%	x		÷	80	)	=	1481	N/A	

<sup>1</sup> Inhalation doses in mg/day are from the Engineering Report generated using ChemSTEER. Unless otherwise stated, the assumption is an 8-hr day. The EPA/OPPT 2-Hands Dermal Contact with Liquids Model calculates worker dermal exposures to a liquid. Model assumptions are:
(1) surface area of contact equals two hands (1,070 cm<sup>2</sup>); (2) high-end default value of quantity remaining on skin = 2.1 mg/cm<sup>2</sup> (low-end default = 0.7 mg/cm<sup>2</sup>); (3) weight fraction of chemical in liquid; (4) 1 contact/worker-day; (5) no use of controls or gloves to reduce exposure; (6) exposure duration = 1 to 4 hours based expectation that worker will, at a minimum, thoroughly wash hands at lunch or end of the day.

### **General Population Calculations:**

 Risks were not identified for general population for developmental toxicity based on analogue data (All MOEs>10,000, Benchmark MOE=1000).

Focus General Population MOE Calculations  MOE = (POD x Abs Rate) / ((PDR x Abs Rate) / BW) Benchmark (acceptable) MOE ≥1000															
Exposure LOAEL Route Acute Dose Route Sensitive Alert/ Exposure Scenarios and (mg/kg/ Absorp Rate Absorp Sub- Component (POD/P													Margin of Exposure (POD/PMN Dose)		
GENERAL POPU	LATION RIS	K					-	•		•		-			
Highest/Worst C	Highest/Worst Case Doses from Exposure Report (LOAEL=1000)														
Drinking Water	( 100	х	100%	)	÷	(	×	100%	х	1.00	х		)	=	177305
Drinking Water	( 100	х	100%	)	÷	(	×	100%	x	4.17	х		)	=	42519
Inhalation	( 100	х	100%	)	÷	(	×	100%	х	1.00	х		)	=	10000

<sup>&</sup>lt;sup>1</sup> General Population and Consumer ingestion Acute Dose Rates are from the Exposure Report and are generated using E-FAST which assumes a 100% absorption rate, and uses an average adult body weight of 80 kg. Consumer ADRs are generated using the Consumer Exposure Module within the E-FAST CBI version called "NCEM2" model.

<sup>&</sup>lt;sup>2</sup> Absorption adjustments for Focus - Assume 100% for POD; For Exposure. If risks, consider adjustments for absorption,etc.

<sup>&</sup>lt;sup>3</sup> USEPA 2011. Exposure factors handbook, final report, EPA/600-R09/052F, 2011, Chapter 8 Body Weight Studies, Table 8-1, Recommended Values for Body Weight http://www.epa.gov/ncea/efh/pdfs/efh-chapter08.pdf

<sup>&</sup>lt;sup>4</sup>Benchmark (Acceptable) MOEs are 100 for NOAEL-based assessment and 1000 for LOAEL-based assessment.

<sup>&</sup>lt;sup>5</sup> Fold factor = value to be applied to bring INHALATION MOE up to acceptable level, used by the CEB Industrial Hygenist to determine respirator recommendations. NOAEL-based fold factor = 100/MOE; LOAEL-based fold factor = 1000/MOE.

<sup>&</sup>lt;sup>2</sup> Absorption adjustments for Focus: Assume 100% POD; if risks, consider adjusting for absorption, etc.

<sup>&</sup>lt;sup>3</sup> Benchmark (Acceptable) MOEs are 100 for NOAEL-based assessment and 1000 for LOAEL-based assessment.

<sup>&</sup>lt;sup>4</sup> Multiplier based on increased drinking water consumption for infants. Multiplier would be less for older populations, so this value is worst-case.

• Consumer Calculations: Risks were not assessed as consumer exposures are not expected.